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REMARKS

Claims 1-7, 10-22, 33, 34, 45 and 47-62 are pending in the application. Claims 23-32, 35-44 and 46 had been cancelled pursuant to an earlier restriction requirement. Claims 8 and 9 were cancelled in a prior Response. Pursuant to the Office Action dated March 30, 2006, all claims stand rejected. By this response, Applicants respectfully request reconsideration of the rejections in light of the following comments.

Claim Rejections

Rejection under 35 USC §103(a) over Trogolo et. al. (US 6,436,422) in view of Michal et. al. (US 6,287,285) and Schink et. al. (US 2001/0009831)

The Patent Office has maintained the rejection of claims 1-7, 10-22, 33, 34, 45 and 47-62 under 35 USC §103(a) as being unpatentable over Trogolo et. al. in view of Michael et. al. and Schink et. al. In setting forth its arguments against patentability, the Examiner endeavors to identify and rebut the various arguments previously set forth by Applicants in support of patentability, as follows.

In responding to Applicants' arguments that Trogolo et. al. disclose liquid hydrophilic coating compositions which, when applied to a substrate and the solvent allowed to evaporate, form an hydrophilic polymer coating or film on the substrate surface, but otherwise make no mention of any utility beyond coating and film forming materials, the Examiner nevertheless asserts that the compositions are obvious. The Examiner states that claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable.

In addressing Applicants' argument that nothing in either Trogolo et. al. or Schink et. al., nor in their combined teachings, suggests, infers or motivates one to form antimicrobial additive particles comprising a plurality of particles of the antimicrobial active agent dispersed in a hydrophilic polymer let alone such particles having an aspect ratio greater than 2, the Examiner essentially states that Trogolo et. al. is cited to show the composition while Schink et. al. "is represented for the disclosure of zeolites added to a polyurethane base material in a particle form to meet the requirement of the claims which recite a microcapsule." The Examiner then goes on to assert that Applicants' admission that the zeolites are in particle form serves the purpose of the rejection. Apparently the Examiner is of the belief and conclusion that zeolites in particle form are inherently microcapsules, stating "it is not an obligation for the Examiner to search the prior art for a microcapsule." (emphasis added)

In addressing Applicants' argument that neither reference teaches or suggests forming micron-sized particles, the Examiner addresses Applicants' attention to the examples of Schink where they employ zeolites in particle form.

Relative to Applicants' arguments concerning the utility and improved performance associated with the use of the claimed high aspect ratio microcapsules, the Examiner states that such properties are not within the scope of the claims and not an issue of examination.

Finally, in addressing Applicants' argument that since nothing in the art suggests the formation of the microcapsules, there is nothing to suggest the further incorporation of a dopant

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into such capsules, the Examiner states that since the antimicrobial zeolites employed in Michal et. al. are inherently in particle form, "...the suggestion of incorporation of a dopant into such particles is acceptable in the rejection.

Applicants respectfully traverse the foregoing arguments and request reconsideration in light of the following arguments.

First, contrary to the assertion of the Examiner, Applicants are not claiming merely a new use, new function or an unknown, yet inherent, property of a known composition. Applicants claim certain compositions of matter having, as a critical aspect, a narrowly defined form. And, regardless of whether the compositions employed in the practice of the present invention are the same as or similar to those of Trogolo et. al, it is well established that a new form of an old composition, especially where the new form is novel and unobvious, is patentable (See e.g., *In re Berry* 315 F2d 916, 137 USPQ 353 (CCPA 1963)). Further, new forms of old compositions are likewise patentable if the differences in the utilities of the new forms are substantial and unobvious (See e.g., *Chas. Pfizer & Co., Inc. v. Barry-Martin Pharmaceuticals* (DCSD Fla. 1965)). Especially pertinent to this discussion is *In re Cofer* (354 F2d 664, 148 USPQ 268 (CCPA 1966)) wherein claims to a free flowing crystalline form of a compound were held unobvious over references disclosing the viscous liquid form of the same compound because the prior art of record did not suggest the claimed compound in crystalline form or how to obtain such crystals (See MPEP 2144.04(VII)).

Both Trogolo et. al. and Schink et. al. describe liquid curable compositions into which antimicrobial zeolite particles are dispersed. These liquid curable compositions are then spread on the substrate to be coated and the composition allowed to 'cure' so as to form a solid antimicrobial polymer coating or film on the substrate treated. Applicants on the other hand claim microcapsules or, if you will, microparticles of hydrophilic polymers having dispersed therein antimicrobial agents, including zeolites. These microparticles have a high aspect ratio and are used as additives for polymer compositions, coatings, and the like. If applied to the surface of a substrate like the coatings of Trogolo et. al. and Schink et. al., these microparticles would readily wash, blow or fall away absent a binder or other coating composition to hold them in place. Thus, while the antimicrobial microparticles of the present invention could be used in substitution for the antimicrobial zeolite additive of the coating compositions of both Trogolo et. al. and Schink et. al., they are not, in and of themselves, substitutes for the whole of the coatings of the cited references. Thus, given the novel form of the antimicrobial hydrophilic compositions as claimed and the substantial and unobvious utility of the same, Applicants' claimed antimicrobial microcapsules are clearly patentable over the cited art.

Second, the Examiner's apparent contention that Applicants' admission that the antimicrobial agents of the cited art are in particle form somehow renders inherent the claimed microcapsules is ridiculous. Is an M&M candy (an encapsulated chocolate) inherent from a Hershey Kiss candy (a non-encapsulated chocolate)? Furthermore, the assertion that the Examiner is under no obligation to search the prior art for microcapsules is ludicrous. Applicants' claims are directed to "[A] high aspect ratio microcapsule" and the use thereof. Applicants are not claiming a composition of matter; rather, they are claiming an article of manufacture of a defined form and composition. (emphasis added) If the examination of the

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instant claims has focused on one but not both aspects, then the Examiner has missed the very essence of the invention.

As noted above, Applicants claim microcapsules or microparticles of a polymer having dispersed therein antimicrobial agents (also in particle form) of defined particle size and aspect ratio. Applicants have found that these microcapsules when added to polymer compositions, including coatings, especially hydrophobic polymer compositions, provide improved antimicrobial properties as compared to such compositions having only the particles of the antimicrobial agents themselves incorporated therein. While Trogolo et. al. and Schink et. al. provide one method for addressing the relatively low antimicrobial performance of antimicrobial additives when incorporated into hydrophobic materials, not all, indeed, very few applications, would be amenable to the use of a hydrophilic coatings. Generally speaking, hydrophilic coatings have poor physical strength and properties, especially wear resistance and the like. However, Applicants have found that by incorporating the same amount of an antimicrobial agent into small particles of a hydrophilic polymer and then incorporating those polymer particles into a hydrophobic polymer, one obtains a marked improvement in antimicrobial activity, as evidenced by ion release, without or with very minimal affect on the overall physical properties of the polymer composition. Clearly, the form and composition of the microparticles are critical to the presently claimed invention.

Third, contrary to the Examiner's assertion that the improved properties are not within the scope of the claims and, therefore, not an issue of examination, the utility and properties are indeed very relevant to the examination of the pending claims. As noted in the above-referenced case law, novelty of form and substantial utility, are important considerations to be undertaken in assessing the patentability of new forms of old compositions. Furthermore, improved properties are clearly relevant to the patentability of the method claim, claim 45. To assert that a composition of matter or article of manufacture is only to be considered in light of its physical make-up without consideration of their appearance, structure, utility or performance capabilities is completely contrary to patent law and practice.

Finally, the assertion that Michal et. al. stand for the incorporation of a dopant into a zeolite particle is absurd. Just how is one to incorporate sodium nitrate, or any dopant salt for that matter, into a zeolite particle? If one mixes two volumes of different solid particles together, one only gets a mixture of the two particles: one is not incorporated into the other. If one attempted to do it by a solution method, one would find that the sodium nitrate would dissolve but the zeolite would not. More importantly, the sodium nitrate would dissociate and the sodium ions would then ion-exchange with the antimicrobial metal ions of the zeolite, thereby depleting it of its antimicrobial active. Certainly not a desirable outcome.

As discussed above, Applicants claim hydrophilic polymer particles of defined dimensions comprising a hydrophilic polymer matrix in which is dispersed particles of an antimicrobial agent and, relative to claims 19-21, a dopant. The claimed particles are employed as antimicrobial additives for polymer compositions, coatings and the like. Trogolo et. al. and Schink et. al. are cited as teaching hydrophilic coatings containing antimicrobial zeolite particles. Wrongly, the Examiner asserts that these compositions are inherently microcapsules. Michal et. al. is cited as teaching "dopants" in hydrophilic coatings. The Examiner asserts that it would have been obvious to combine the teachings of the former with the latter to arrive at

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Applicants' claimed microcapsules. As noted above, nothing in the individual or combined teachings of the cited references suggest the claimed high aspect ratio antimicrobial hydrophilic polymer particles. Thus, for the reasons set forth above as to the patentability of the claimed microcapsules themselves, the modified microcapsules containing the dopant are likewise patentable.

The patentability of the claimed microcapsules over the prior art antimicrobial coatings aside, Applicants believe even a coating composition comprising the combination of a dopant and an antimicrobial hydrophilic coating would have been patentable over the combined teachings of the cited art. Michal et. al. suggest a myriad of therapeutic agents that may be employed in the therein claimed coatings. Among the various therapeutic agents suggested are nitric oxide donors, including sodium nitrate, which are employed as smooth muscle relaxants; however, Michal et. al. exemplify none of these nitric oxide donors. Furthermore, nowhere does Michal et. al. suggest or infer that these nitric oxide donors, or sodium nitrate in particular, have the ability to act as a dopant: an additive material that increases the amount of sodium or other ion-exchangeable cations available over that naturally found in the end-use application in order to expedite the initiation of and increase the rate of release of the antimicrobial metal ions from the antimicrobial zeolites. Indeed, but for sodium nitrate and, perhaps, sodium nitroprusside, none of the suggested nitric oxide donors of Michal et. al. would even act as a dopant.

Furthermore, despite all of the various therapeutic agents suggested in Michal et. al., Michal et. al. makes no mention, suggestion or inference of the use of antibiotics, antibacterial agents or antimicrobial agents. Even if one were somehow motivated to add the antimicrobial agent of Trogolo et. al. to one of the several types of coatings of Michal et. al., nothing in Michal et. al. would necessarily point one to select a coating that is both therapeutic and hydrophilic, let alone select a nitric oxide donor as the therapeutic agent, or, more importantly, to select a nitric oxide donor that is capable of releasing sodium cations for participation in an ion exchange process involving the antimicrobial agent. Indeed, the only selection process that has any remote possibility of arriving at this combination would be one that involves an article of manufacture to be employed in association with smooth muscles. If not, then Michal et. al. would have no reason to employ a nitric oxide donor. Regardless, even if, through some remote series of coincidences, one did arrive at the combination of sodium nitrate and antimicrobial zeolites in a hydrophilic coating, nothing would have predicted the enhancement of antimicrobial metal ion release. Given the lack of motivation for arriving at the specific combination of components, out of the myriad of possible combinations presented, and the unexpected results obtained by the specific combination of a hydrophilic matrix with an ion-exchange type antimicrobial agent and sodium nitrate dopant, the specific combination would clearly have been patentable over Trogolo et. al. and Michal et. al. In following, this combination of constituents in the specific and unobvious form as currently claimed is likewise patentable.

Conclusion

Applicants believe that they have fully addressed and rebutted each of the rejections under 35 USC 103(a) as well as each of the rebuttals to Applicants' prior arguments made by the Examiner in the Final Office Action. Applicants believe that the claims, as now presented, are in allowable form. However, if the Examiner has not previously considered or examined the form of the compositions as claimed, i.e., the microcapsules, then Applicants hereby request that

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such a search and examination now be undertake. On the other hand, if Applicants' representative is mistaken and such factors have been considered in the searches and examination of the pending claims to date, then Applicants respectfully request that the claims, as presented, be passed on to allowance in light of the foregoing discussion.

Should there be any questions; the Examiner is kindly requested to contact the undersigned, Applicant's attorney.

Respectfully submitted,



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